

**NOT FOR PUBLICATION**

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

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CIMA LABS, INC. and SCHWARZ :  
PHARMA, INC., :  
: Plaintiffs, :  
: v. : : Civ. No. 07-893 (DRD)  
: :  
ACTAVIS GROUP HF, ACTAVIS, INC. :  
and ACTAVIS ELIZABETH, LLC, :  
: Defendants. :  
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**O P I N I O N**

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CIMA LABS, INC. and SCHWARZ :  
PHARMA, INC., :  
: Plaintiffs, :  
: v. : : Civ. No. 06-1970 (DRD)  
: : (Consolidated with 06-1999 (DRD))  
PAR PHARMACEUTICAL COMPANIES, :  
INC., PAR PHARMACEUTICAL, INC. :  
and KALI LABORATORIES, INC., :  
: Defendants. :  
:

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**DEBEVOISE, Senior District Judge**

**I. PROCEDURAL HISTORY**

Plaintiffs, Cima Labs, Inc. (“Cima”) and Schwarz Pharma, Inc. (“Schwarz Pharma”) (collectively, “Plaintiffs”) each instituted patent infringement actions against defendants Par Pharmaceutical Companies, Inc., Par Pharmaceutical, Inc., and Kali Laboratories, Inc. (the “Par/Kali Defendants”) alleging infringement of U.S. Patent No. 6,024,981 (the “‘981 patent”) and U.S. Patent No. 6,221,392 (the “‘392 patent”) (the “patents”). By stipulation and order dated January 25, 2007, those cases were consolidated (the “Par case”). Subsequently, on February 23, 2007, Plaintiffs instituted a patent infringement action against defendants, Actavis Group hf<sup>1</sup>, Actavis, Inc., and Actavis Elizabeth LLC, alleging infringement of the patents (the “Actavis case”).

There are currently four motions pending before the court: (1) Actavis’s motion to dismiss the Complaint in the Actavis case pursuant to Fed. R. Civ. P. 12(b)(6); (2) Actavis’s motion to seal portions of the brief and exhibits filed in its motion to dismiss; (3) Cima’s motion to temporarily stay the proceedings in both the Actavis case and the Par case; and (4) Cima’s motion to consolidate the Actavis case and the Par case. For the reasons set forth below, Actavis’s motion to dismiss will be denied and its motion to seal will be granted, and Cima’s motion to consolidate and motion to stay will be granted.

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<sup>1</sup>The present motion to dismiss was filed by Actavis, Inc. and Actavis Elizabeth LLC (“Actavis”) and does not include Actavis hf.

## **II. BACKGROUND**

The Actavis case and the Par case are patent infringement actions arising under the Hatch-Waxman Act. In both cases the defendants have sought approval from the FDA to sell a generic version of the prescription drug NIRAVAM™, an alprazolam product.

The invention covered by both of the patents is known to produce an in-mouth disintegrable dosage form for the delivery of drugs. (Col. 1, ll. 12-13). The invention relates to a hard, compressed, rapidly dissolvable dosage form adapted for direct oral dosing. (Col. 2, ll. 5-7). The dosage form includes an active ingredient and a matrix. (Col. 2, ll. 7-8). The matrix is composed of at least a non-direct compression filler and a lubricant. (Col. 2, ll. 8-9). The dosage form is adapted to rapidly dissolve in the mouth of a patient and thereby liberate the active ingredient. (Col. 2, ll. 9-11).

Plaintiffs' complaint in the Actavis case (the "Complaint") alleges the following:

On February 15, 2000, the United States Patent and Trademark Office (the "PTO") issued the '981 patent, entitled "Rapidly Dissolving Robust Damage Form." (Compl. ¶ 13). An *ex parte* reexamination of the '981 patent was requested on or about August 22, 2005, and reexamination was ordered on or about October 7, 2005. (Id. at ¶ 14). A second *ex parte* reexamination was filed on or about September 7, 2006, and reexamination was ordered on or about September 28, 2006. (Id.). The two reexaminations were consolidated on or about January 8, 2007. (Id.). By way of assignment, Cima owns all rights, title, and interest in and to the '981 patent, including the right to sue and recover for patent infringement. (Id. at ¶ 15).

On April 24, 2001, the PTO issued the '392 patent, entitled "Rapidly Dissolving Robust Damage Form." (Id. at ¶ 16). An *inter partes* reexamination was filed on July 28, 2006, and

reexamination was ordered on or about September 13, 2006. (Id. at ¶ 17). By way of assignment, Cima owns all rights, title, and interest in and to the ‘392 patent, including the right to sue and recover for patent infringement. (Id. at ¶ 18).

Schwarz Pharma is the exclusive licensee to the ‘981 and ‘392 patents for alprazolam orally disintegrating tablets in the United States. (Id. at ¶ 19). Under the exclusive license, Cima manufactures NIRAVAM™, an alprazolam product, for Schwarz Pharma. (Id.). The ‘981 and ‘392 patents are listed in the Orange Book (formerly entitled *Approved Drug Products with Therapeutic Equivalence Evaluations*) as covering NIRAVAM™, alprazolam orally disintegrating tablets on 0.25 mg, 0.5 mg, 1 mg, and 2mg dosages. (Id. at ¶ 20).

Actavis Elizabeth LLC submitted an Abbreviated New Drug Application (“ANDA”), No. 78-561, to the United States Food and Drug Administration (“FDA”) pursuant to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j) (the “ANDA”). (Id. at ¶ 21). Actavis filed the ANDA seeking the approval of the FDA necessary to engage in the commercial manufacture, use, offer for sale and sale of generic versions of alprazolam orally disintegrating tablets in 0.25 mg, 0.5 mg, 1mg, and 2 mg dosages. (Id.).

No earlier than January12, 2007, Plaintiffs received a letter from Actavis notifying them that the ANDA containing a Paragraph IV Certification had been submitted to the FDA (the “Paragraph IV Notice Letter”). (Id. at ¶ 22). The Paragraph IV Notice Letter and the ANDA allege that the ‘981 and ‘392 patents are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of the generic versions of alprazolam orally disintegrating products for which Actavis seeks FDA approval. (Id.).

Plaintiff’s allegations in Counts One and Two are identical with respect to each patent.

Plaintiffs allege that Actavis's submission of the ANDA to the FDA constitutes infringement of the '981 and '392 patents under 28 U.S.C. § 271(e)(2)(A). (*Id.* at ¶ 25, 31). Plaintiffs also allege that Actavis's manufacture, use, offer for sale and/or sale of its proposed generic versions for which Actavis seeks approval from the FDA under the ANDA will infringe, contribute to the infringement of and induce infringement of one or more of the claims of the '981 and '392 patents. (*Id.* at ¶ 26, 32). Plaintiffs further allege that Actavis was aware at the time of submission of the ANDA, and continues to be aware, that the proposed generic versions, if approved, will be made, used and/or sold in contravention of Plaintiffs' rights in and to the '981 and '392 patents. (*Id.* at ¶ 27, 33). Plaintiffs allege that the conduct by Actavis renders this case "exceptional" as described in 35 U.S.C. § 285. (*Id.* at ¶ 28, 34).

In their prayer for relief, Plaintiffs seek: (1) a judgment that Actavis has infringed the '981 and '392 patents; (2) an order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing the effective date of any approval of the ANDA be subsequent to the date of the last to expire of the patents; (3) a preliminary and permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B); (4) monetary relief and damages pursuant to 35 U.S.C. § 284; (5) a declaration that this case is exceptional under 35 U.S.C. § 271(e)(4)(C) and 35 U.S.C. § 285; and (6) attorneys' fees and costs. (Compl. at p. 7-8).

The complaints filed in the consolidated Par case contain similar allegations. Each complaint alleges infringement based on the Par/Kali Defendants' submissions of ANDAs to the FDA seeking approval of the FDA necessary to engage in the commercial manufacture, use, and sale of generic versions of alprazolam tablets.

### **III. DISCUSSION**

**A. Actavis's Motion to Dismiss**

**1. Standard for Dismissal under Fed. R. Civ. P. 12(b)(6)**

Dismissal of a complaint pursuant to Rule 12(b)(6) is proper "only if it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations." Hishon v. King & Spalding, 467 U.S. 69, 73. Allegations contained in the Complaint will be accepted as true, Cruz v. Beto, 405 U.S. 319, 322 (1972), and Plaintiff shall be "given the benefit of every favorable inference that can be drawn from those allegations." Schrob v. Catterson, 948 F.2d 1402, 1405 (3d Cir. 1991). However, the plaintiff is required to make factual allegations and cannot rely on conclusory recitations of law. Pennsylvania ex rel. Zimmerman v. Pepsico, Inc., 836 F.2d 173, 179 (3d Cir. 1988).

**2. Infringement**

Actavis's first argument is premised on their construction of certain terms in the patents. Actavis contends that there is no patent infringement because the patent claims themselves all use the term "non-direct compression filler." (Defs.' Br. 12). Actavis claims that the specifications of the patents "repeatedly state that the use of non-direct compression fillers is a feature of the invention, and that non-direct compression fillers are different and distinct from a [sic] direct compression fillers." (Id.). Actavis argues that under the ordinary meaning of the term "non-direct," a "non-direct compression filler" could not be construed as "direct compression filler," the type of filler used in the proposed Actavis product. (Id. at 12-13).

Because the court finds that "the proper time for this Court to address claim construction is not in a motion to dismiss[,]" Schreiber v. Eli Lilly & Co., No. Civ. A. 05CV2616, 2006 WL 782441, at \*4 (E.D. Pa. 2006) (citing Markman v. Westview Instruments, Inc., 517 U.S. 370

(1996)), this argument fails.

Additionally, Actavis contends that during the prosecution of the ‘392 patent, Cima “represented to the PTO that its patent claims were limited to non-direct, as opposed to direct, compression fillers.” (Id. at 12). Actavis claims that as a result of Cima’s representations to the PTO, Cima is now estopped from asserting that direct compression fillers are equivalent to the claimed “non-direct compression fillers” under the doctrine of equivalents. (Id. at 15). Actavis contends that “[b]ecause Actavis’ proposed products contains [sic] only direct compression fillers, they do not contain each and every element of the claims of the asserted patents.” (Id.). Actavis asserts that as a result, its products do not infringe any of the asserted patent claims as a matter of law. (Id.).

Finally, Actavis contends that because the ANDA specifies the exact fillers that it will use in its products after FDA approval and the fillers fall outside of the claims of the patents, Actavis’s proposed products do not infringe the patents. (Defs.’ Br. 17). Actavis also argues that it is bound by the ANDA because “[i]f Actavis makes any misstatements in its ANDA under 21 U.S.C. § 335b(a)(1), it can be subject to civil penalties.” (Id. at 17-18). Lastly, Actavis contends that because it must seek FDA approval for any changes to the ANDA, the products Actavis sells must conform with the information in the ANDA. (Id. at 18). Actavis argues that “this information demonstrates that Actavis’ alprazolam products will not infringe the claims of the Cima ‘981 and ‘392 patents.” (Id.).

Actavis has attached several documents as exhibits to its motion. Included in those documents are: (1) Plaintiffs’ response to an office action of the PTO rejecting claim 1 of the application that ultimately issued as the ‘392 patent; and (2) portions of the ANDA.

“As a general matter, a district court ruling on a motion to dismiss may not consider matters extraneous to the pleadings.” In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1426 (3d Cir. 1997). However, “a ‘document *integral to or explicitly relied* upon in the complaint’ may be considered ‘without converting the motion [to dismiss] into one for summary judgment.’” Id. (alteration in original) (quoting Shaw v. Digital Equip. Corp., 82 F.3d 1194, 1220 (1st Cir. 1996)). “The rationale underlying this exception is that the primary problem raised by looking to documents outside the complaint-lack of notice to the plaintiff-is dissipated ‘[w]here plaintiff has actual notice . . . and has relied upon these documents in framing the complaint.’” Id. (alteration in original) (quoting Watterson v. Page, 987 F.2d 1, 3-4 (1st Cir. 1993)).

Here, Plaintiff’s response to the PTO’s office action is not integral to or explicitly relied upon in the Complaint. Therefore, this document will not be considered. Additionally, although Plaintiffs refer to the ANDA in the Complaint, the reference is merely to the fact that the ANDA was filed and to describe generally the contents of the ANDA that was gleaned from the Paragraph IV Notice Letter. Thus, because Plaintiffs did not explicitly rely on the ANDA document, the ANDA will not be considered on this motion. Furthermore, even if the ANDA was considered by the court, its filing by Actavis is not determinative of the infringement issue.

In support of their argument that the ANDA demonstrates that the fillers used in their proposed product fall outside of the claims of the patents, Actavis relies on Bayer AG v. Elan Pharm. Research Corp., 212 F.3d 1241 (Fed. Cir. 2000) for the proposition that where the specification in the ANDA defines the product in a way that directly addresses the question of infringement, the ANDA applicant will be bound by that specification. However, although

Actavis may be bound, this is not determinative of the infringement issue, especially on a motion to dismiss where issues of claim construction exist and where there has been little or no discovery.<sup>2</sup>

“[I]n order to survive a motion to dismiss, ‘a patentee need only plead facts sufficient to place the alleged infringer on notice.’” Schreiber v. Eli Lilly & Co., No. Civ. A. 05CV2616, 2006 WL 782441, at \*4 (E.D. Pa. 2006) (quoting Phonometrics, Inc. v. Hospitality Franchise Sys., Inc., 203 F.3d 790, 794 (Fed. Cir. 2000)). Here, Plaintiffs have alleged that Schwarz Pharma is the exclusive licensee to the patents and that Actavis has infringed the patents. Thus, Plaintiffs have pleaded sufficient facts to place Actavis on notice of their claims, and as a result, Actavis’s motion will be denied. See Schreiber, 2006 WL 782441, at \*4 (finding plaintiffs pleaded sufficient facts to put defendant on notice of their patent infringement claims).

**B. Actavis’s Motion to Seal**

In its motion, Actavis seeks to seal portions of the memorandum of law in support of its motion to dismiss and certain exhibits of counsel’s declaration in support of the motion to dismiss. This motion is unopposed.

Pursuant to Local Civil Rule 5.3(c), a party may request to seal materials by filing a formal motion pursuant to Local Civil Rule 7.1. L. Civ. R. 5.3(c)(1). The motion papers must describe: (a) the nature of the materials or proceedings at issue; (b) the legitimate private or public interests which warrant the relief sought; (c) the clearly defined and serious injury that would result if the relief sought is not granted, and (d) why a less restrictive alternative to the relief sought is not available. L. Civ. R. 5.3(c)(2).

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<sup>2</sup>Bayer was decided on a motion for summary judgment.

Counsel for Actavis has submitted a certification in support of this motion (“McShane Cert.”). In the certification, counsel sets forth the nature of the materials as, *inter alia*, constituting or disclosing trade secrets and confidential and proprietary information. (McShane Cert. ¶ 5). Counsel states that the action involves confidential technical information regarding a proposed product that Actavis has a legitimate interest in protecting. (Id. at ¶ 7-8). Furthermore, counsel certifies that trade secrets would be lost if competitors gained access to the materials, which would result in a loss to Actavis. (Id. at ¶ 10). Finally, counsel states that no less restrictive alternative is available to prevent the injury. (Id. at ¶ 11).

The court finds that Actavis has satisfied the factors set forth in L. Civ. R. 5.3(c)(2) and therefore will grant the motion to seal.

**C. Cima’s Motion to Consolidate**

\_\_\_\_\_ Cima has moved to consolidate the Par case and the Actavis case pursuant to Fed. R. Civ. P. 42(a). Rule 42(a) provides:

When actions involving a common question of law or fact are pending before the court, it may order a joint hearing or trial of any or all the matters in issue in the actions; it may order all the actions consolidated; and it may make such orders concerning proceedings therein as may tend to avoid unnecessary costs or delay.”

Fed. R. Civ. P. 42(a). “The purpose of consolidation is ‘to streamline and economize pretrial proceedings so as to avoid duplication of effort, and to prevent conflicting outcomes in cases involving similar legal and factual issues.’” In re TMI Litig., 193 F.3d 613, 724 (3d Cir. 1999) (quoting In re Prudential Sec. Inc. Ltd. P’ships Litig., 158 F.R.D. 562, 571 (S.D.N.Y. 1994)). The moving party bears the burden of proof on a motion for consolidation. In re Consol. Parlodel Litig., 182 F.R.D. 441, 444 (D.N.J. 1998).

Although a common question of law or fact shared by the cases is a prerequisite for consolidation, the mere existence of common issues does not require consolidation. Id. “Once a common question of law or fact has been established, the decision to consolidate rests in the sound discretion of the district court.” Id. The court, in exercising its discretion, “should weigh ‘the interests of judicial economy against the potential for new delays, expense, confusion, or prejudice.’” Id. (quoting Easton & Co. v. Mut. Benefit Life Ins. Co., 1992 WL 448794, at \*4 (D.N.J. Nov. 4, 1992)). “In this analysis, however, ‘[c]onsiderations of convenience and economy must yield to a paramount concern for a fair and impartial trial.’” Id. (quoting Johnson v. Celotex Corp., 899 F.2d 1281, 1285 (2d Cir. 1990)).

Cima contends that the Par and Actavis cases should be consolidated because of the following similarities between the two cases: (1) the patents-in-suit are the same; (2) the plaintiffs are the same; (3) the two ANDAs at issue relate to the generic formulation of the same patented drug; (4) the legal issues relating to both infringement and validity will be the same; (5) both defendants assert noninfringement based on the materials and process used in creating the equivalent generic version; (6) the defendants’ validity arguments will both involve consideration of the same prosecution history, prior art, and expert testimony; (7) Markman briefing and hearings will be directed to the same issues; and (8) the legal relief sought is the same. (Cima’s Br. 5-7).

In support of its position, Cima relies primarily on Smithkline Beecham Corp. v. Geneva Pharm., Inc., 2001 WL 1249694 (E.D. Pa. 2001). In that case, defendant companies that manufactured generic drugs filed ANDAs for generic forms of the antidepressant drug PAXIL®, which plaintiff alleged infringed on one or more of its patents. The court granted a motion to

consolidate the several related actions for pretrial purposes. The court found that:

Although the defendants have submitted five separate ANDAs for their generic formulations of the drug, there is substantial overlap among the patents they are alleged to have infringed. Issues of patent validity are therefore common to all defendants whose ANDA implicates a particular patent. Further, it does not appear that discovery in the earliest-filed actions is so far advanced that pretrial consolidation would be inefficient or prejudicial to the parties.

Id. at \*5.

Additionally, Cima argues that judicial economy supports consolidation. (Cima's Br. 7).

Cima contends that because of the similarities between the two cases, a significant portion of discovery will be the same, and a coordinated discovery plan will alleviate the need for duplicative discovery. (Id. at 8). Cima also contends that discovery in both cases is at an early and identical stage. Cima asserts that there has been no discovery in the Actavis case, and in the Par case, the only discovery has been the exchange of initial written discovery and objections. (Id.). Finally, Cima contends that consolidation minimizes the risk of conflicting results at trial and that the risk of any prejudice is minimal because consolidation assures consistent application of the facts and law in both cases. (Id. at 8-9).

Actavis sets forth several reasons for its opposition to consolidate. First, Actavis contends that the Par and Actavis cases likely involve different products and noninfringement positions. (Actavis's Br. 8). Although Actavis concedes that it doesn't know the details of Par's proposed products because that information is part of Par's confidential ANDA, Actavis argues that its own products do not infringe and that Par's products are likely more complicated and require additional discovery, given the schedule in the Par case. (Id.). Actavis contends that with different products likely at issue, the bases of noninfringement asserted by Actavis and Par will

likely differ. (Id.).

Second, Actavis argues that the actions should not be consolidated because they are on two different discovery schedules. (Id. at 9). Actavis contends that: (1) in the Par case, fact discovery is set to close on May 21, 2007 and expert discovery to close in about six months; (2) while no discovery has commenced in the Actavis case, the Actavis case can progress more quickly than the Par case; (3) there has been minimal progress of discovery in the Par case; and (4) no motions to compel discovery have been filed by either party in the Par case. (Id.). Actavis argues that based on the discovery history, no party has demonstrated an intent to progress on a timely basis, and the discovery schedule is likely to be extended.<sup>3</sup>

Third, Actavis contends that the issues in the Actavis case are clear and can be disposed of quickly. (Id.). Actavis argues that its motion to dismiss makes it clear that its accused products do not infringe and that its noninfringement positions are clear and simple on both factual and legal grounds. (Id.). Actavis contends that it is prepared to provide discovery to Cima on an expedited basis which “will allow early disposition of the action, thereby avoiding extended, unnecessary discovery and promoting judicial economy.” (Id. at 10).

Fourth, Actavis contends that consolidation would result in prejudice. Actavis argues that it will be prejudiced: (1) by extended, unnecessary, and costly discovery; (2) by tying the Actavis case to Par’s schedule; and (3) if the concurrent motion to stay by Cima is also granted. (Id.).

Initially, the court finds that there is a common question of law or fact shared by the cases. Both cases involve the ‘981 and ‘392 patents and ANDAs that were submitted by the

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<sup>3</sup>Subsequent to the filing of Actavis’s Opposition, by order dated May 23, 2007, the Magistrate Judge assigned to the Par case extended discovery to July 11, 2007.

Par/Kali Defendants and Actavis seeking the approval of the FDA necessary to engage in the commercial manufacture and sale of generic versions of NIRAVAM™, an alprazolam product. Thus, the issues of infringement and validity will likely be similar. However, this does not end the inquiry, as the court is required to exercise its discretion in weighing “the interests of judicial economy against the potential for new delays, expense, confusion, or prejudice.” In re Consol. Parlodel Litig., 182 F.R.D. at 444.

Here, the interests of judicial economy outweigh the potential for delays, expense, confusion, or prejudice. As discussed, the cases involve common questions of law and fact, which makes coordinated discovery appropriate. Similarly, consolidation will avoid duplication of efforts by the parties. Finally, although the Par case was filed earlier than the Actavis case, it does not appear that discovery has advanced to the point that consolidation would be inefficient or prejudicial to the parties. See Smithkline, 2001 WL 1249694 at \*5. Therefore, Cima’s motion to consolidate will be granted for pre-trial purposes.

**D. Cima’s Motion to Stay**

Finally, Cima moves to temporarily stay the proceedings in both the Actavis case and the Par case. The district court’s power to stay a proceeding “is incidental to the power inherent in every court to schedule disposition of the cases on its docket so as to promote fair and efficient adjudication.” Gold v. Johns-Manville Sales Corp., 723 F.2d 1068, 1077 (3d Cir. 1983) (citing Landis v. N. Am. Co., 299 U.S. 248, 254-55 (1936)). This power “calls for the exercise of judgment, which must weigh competing interests and maintain an even balance[,]” Landis, 299 U.S. at 254-55, and includes “the authority to order a stay pending conclusion of a PTO reexamination.” Ethicon, Inc. v. Quigg, 849 F.2d 1422, 1428 (Fed. Cir. 1988) (citing Gould v.

Control Laser Corp., 705 F.2d 1340, 1342 (Fed. Cir. 1983)). “The party seeking the stay must demonstrate ‘a clear case of hardship or inequity, if there is even a fair possibility that the stay would work damage on another party.’” Hertz Corp. v. The Gator Corp., 250 F. Supp. 2d 421, 424 (D.N.J. 2003) (quoting Gold, 723 F.2d at 1075-76).

In deciding whether to grant a stay, the court must weigh the benefits against the costs and consider: (1) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party; (2) whether a stay would simplify the issues and the trial of the case; and (3) whether discovery is complete and/or a trial date has been set. Motson v. Franklin Covey Co., No. Civ. 03-1067, 2005 WL 3465664, at \*1 (D.N.J. Dec. 16, 2005).

The legislative history of the Patent Act of 1980 described the goal of the patent reexamination procedure as follows:

Reexamination will permit efficient resolution of questions about the validity of issued patents without recourse to expensive and lengthy infringement litigation. . . . A new patent reexamination procedure is needed to permit the owner of a patent to have the validity of his patent tested in the patent office where the most expert opinions exist and at a much reduced cost. . . . The reexamination of issued patents could be conducted with a fraction of the time and cost of formal legal proceedings and would help restore confidence in the effectiveness of our patent system. The bill does not provide for a stay of court proceedings. It is believed by the committee that stay provisions are unnecessary in that such power already resides with the court to prevent costly pretrial maneuvering which attempts to circumvent the reexamination procedure. It is anticipated that these measures provide a useful and necessary alternative for challengers and for patent owners to test the validity of United States patents in an efficient and relatively inexpensive manner.

H.R. Rep. 96-1307(I) (Sept. 9, 1980).

Although the court is cognizant that the procedure may not operate as expeditiously as

some may have expected, see Rohm & Haas Co., 24 U.S.P.Q. 2d 1369, 1372 (D. Del. 1992) (noting that a stay may add eighteen months to the time for resolution of the case), reexamination proceedings, including any appeal to the Board of Patent Appeals and Interferences, are to be conducted “with special dispatch.” 35 U.S.C. § 305. The term “special dispatch” has been found to “envision[ ] some type of unique, extraordinary, or accelerated movement.” Ethicon, 849 F.2d at 1426.

At least one court has expressly noted that “there is a liberal policy in favor of granting motions to stay proceedings pending the outcome of USPTO reexamination or reissuance proceedings.” ASCII Corp. v. STD Entm’t USA, Inc., 844 F. Supp. 1378, 1381 (N.D. Cal. 1994). This liberal policy exists in large part because of the “simplification of litigation that might result from the cancellation, clarification, or limitation of claims, and, even if the reexamination did not lead to claim amendment or cancellation, it could still provide valuable analysis to the district court.” Ethicon, 849 F.2d at 1428; see also, GPAC, Inc. v. D.W.W. Enters., Inc., 144 F.R.D. 60, 63 (D.N.J. 1992) (finding PTO may be in better position to evaluate validity of patent and that reexamination procedure “was clearly intended to provide the federal courts with the expertise of the PTO.”)

Here, Cima contends that a stay does not prejudice or tactically disadvantage defendants because in both the Actavis case and the Par case, defendants have not invested substantial time in the litigation. (Cima’s Br. 4). Furthermore, Cima argues that any delay caused by the reexaminations will be minimal because not only is the PTO required to handle a reexamination with “special dispatch,” but the patents in suit are well into the reexamination process. (Id. at 5). Cima contends that the patents have been in reexamination for approximately eighteen months

and that the patentees' responses will be decided upon by the PTO examiner within the next four to six months. (Id.). Cima also argues that because during reexamination claims cannot be broadened and can only be narrowed, cancelled, or affirmed, staying the cases will not harm Actavis or Par. (Id. at 5-6). Cima contends that if the court does not enter a stay, the parties will have to litigate claims that may or may not exist following reexamination. (Id. at 6).

Additionally, Cima contends that there is no tactical disadvantage to defendants because discovery is in the early stages and no trial date has been set. (Id.). Furthermore, Cima contends that reexamination will simplify the issues in question and that awaiting the results of reexamination promotes judicial economy. (Id. at 7). Finally, Cima argues that the fact there has been no discovery in the Actavis case and very little discovery in the Par case weighs heavily in favor of granting a stay.

In opposition to Cima's motion to stay the proceedings, Par contends that a stay will result in prejudice and a tactical disadvantage. (Par's Br. 11). It explains that the nature of the litigation under the Hatch-Waxman Act implicates timing and delay concerns related to the 30-month stay of FDA approval. See 21 U.S.C. § 355(j)(5)(B)(iii) (approval by the FDA shall be made effective upon the expiration of the 30-month period beginning on the date of receipt of the notice that the ANDA containing a Paragraph IV Certification had been submitted to the FDA). (Id.). Par contends that because the FDA cannot approve Par's ANDA until 30 months from the date Par received its notice letter (September 22, 2008) or until the litigation is resolved in its favor, Cima's ability to continue the reexamination process ensures that the earlier of the two dates will be September 22, 2008. (Id.). Par argues that the result is a brand monopoly by Cima and Schwarz and a loss of revenue to Par. (Id.). Par also contends that although Cima states that

the reexamination process will take another four to six months, that estimate does not take into account Cima’s options to seek a reopening of the proceeding with the patent examiner, to appeal the decision to the Board, and to appeal the Board’s decision to the Federal Circuit. (Id. at 12).

Additionally, Par argues that a stay will prejudice it by potentially exposing it to damages that would not exist if the case was resolved before the expiration of the 30-month stay. (Id.). Par contends that if Cima were to prevail in the litigation, the only damages available to Cima would be exceptional case attorney’s fees because Par has not yet marketed a generic NIRAVAM™ product. (Id.). Par argues that if the litigation is ongoing after the 30-month period, Par will be faced with “the Hobson’s choice of either marketing its product under a cloud of uncertainty and risking millions of dollars in potential liability, or refrain from marketing its product until the litigation has ended.” (Id. at 12-13). Finally, Par contends that because the PTO has twice rejected Cima’s patent claims, Cima has prevented Par from offering a generic NIRAVAM™ product. (Id. at 13).<sup>4</sup> <sup>5</sup> <sup>6</sup>

The court finds that factors weigh in favor of granting a stay. First, although Par may be prejudiced to some degree by a delay in the litigation, Par’s argument that Cima will dictate the

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<sup>4</sup>Par fails to address: (1) whether a stay would simplify the issues in the case; and (2) whether discovery is complete and/or a trial date has been set.

<sup>5</sup>Par requests that if the court grants the motion to stay, that the court order that the stay of the action be conditioned on the shortening of the 30-month stay of FDA approval of Par’s ANDA and that the order state that the stay does not toll the running of the 30-month stay of FDA approval. Par cites 21 U.S.C. § 355(j)(5)(B)(iii) which states, in part, that the court may shorten the 30-month stay if “either party to the action failed to reasonably cooperate in expediting the action . . .”

<sup>6</sup>Par also requests that if the court grants the motion to stay and Actavis’s motion to dismiss, that it be granted leave to file a motion for summary judgment. Having denied Actavis’s motion to dismiss, this argument is moot.

length of that delay is speculative. Additionally, any delay “would not be for such a protracted or indefinite period to constitute an abuse of discretion.” Motson, 2005 WL 3465664, at \*1 (citing Gould, 705 F.2d at 1341-42). Second, a stay pending reexamination would likely simplify the issues in both cases because it may result in the cancellation, clarification, or limitation of the claims. Similarly, given the expertise of the PTO, its findings would provide a valuable analysis to the court. Third, discovery is in its beginning stage in both cases with a trial date far from being set. Indeed, “[m]ost often, cases have been denied a stay due to the late stage of litigation, the fact that discovery was or would be almost completed, or the matter had been marked for trial.” GPAC, 144 F.R.D. at 64. Here, none of those concerns are present.

Finally, although Par requests certain conditions on the stay, its reliance on 21 U.S.C. § 355(j)(5)(B)(iii) is misplaced, and it fails to cite any case law to support its argument. Thus, Cima’s motion to stay the proceedings will be granted.

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#### **IV. CONCLUSION**

For the reasons set forth above, Actavis’s motion to dismiss will be denied and its motion to seal will be granted, and Cima’s motion to consolidate and motion to stay will be granted. The court will enter an order implementing this opinion.

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/s/ Dickinson R. Debevoise

DICKINSON R. DEBEVOISE, U.S.S.D.J.

Dated: June 7, 2007